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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,014	08/15/2001	Barry Ross Matthews	017227-0179	8363

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WASHINGTON, DC 20007

EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 04/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/929,014	Applicant(s) MATTHEWS ET AL.	
	Examiner Jeffrey E. Russel	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2001 and 25 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/230,189.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> | 6) <input type="checkbox"/> Other: |

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1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

The claim for priority should also refer to the PCT application upon which priority is claimed.

2. Page 16, line 14, and page 18, Table 3, of the instant specification were not amended as were the corresponding sections of the parent specification. Further, in order to be consistent with the amendments made to the parent specification, at page 20, seventh line of the table, "MV" should also be changed to "CMV". Appropriate correction is required.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-31 and 33-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure supporting the new claim limitations in claim 17 that the anionic-containing moiety can be an aryl or arylalkyl

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anionic moiety, a heteroaryl or heteroarylalkyl anionic moiety, or a quaternary nitrogen-containing moiety. There is no literal support for the claim limitations in the original disclosure of the invention, nor are the claim limitations disclosed using equivalent terminology. While there are a few species of aryl or arylalkyl anionic moieties and a single species heteroaryl or heteroarylalkyl anionic moiety disclosed at pages 4-6 of the specification, the limited number of species do not provide support for the significantly larger genres now recited in the claims, especially where the generic terminology, i.e. aryl, arylalkyl, heteroaryl, and heteroarylalkyl, is not even related to the functional part of the molecules, i.e. the anionic portion. There are only a few species of a quaternary nitrogen-containing moiety disclosed at pages 4-6 of the specification, and all are trimethylammonium-containing moieties. The disclosure of a limited number of species does not provide support for the significantly larger genus now recited in the claims. Further, Applicants argued in the response filed January 11, 2001 in parent application 09/230,189 (see pages 10-11) that their particular anionic and cationic groups result in unexpected activity. Where it is clear, for instance, that the broad described range pertains to a different invention than the narrower (and subsumed) claimed range, then the broader range does not describe the narrower range. In re Wertheim, 191 USPQ 90, 98 (CCPA 1976). Accordingly, Applicants' broadest original disclosure, "anionic- or cationic-containing moiety", does not constitute an adequate written description of the current claim language because the current claim language is alleged to possess unexpected results in comparison to anionic- or cationic moieties in general, and is thus directed to a different invention than Applicants' broadest original disclosure. The specification does not clearly indicate that at the time the invention was

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made, inventors contemplated these particular definitions or categories of the anionic and cationic groups.

4. Claims 30 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear how the claim limitations of claim 30 are to be reconciled with those of claim 17. While claim 17 now requires the anionic or cationic groups to be aryl or arylalkyl anionic moieties, heteroaryl or heteroarylalkyl anionic moieties, neuraminic or sialic acid-containing moieties modified by substitution at the 4-position, or quaternary nitrogen-containing moieties, only the third and fourth members of the Markush group of claim 30 explicitly require the groups recited in independent claim 17. It is not clear how the other members of the Markush group of claim 30 should be interpreted. One possible interpretation is that, for example, if at least one sulfonic acid containing moiety is present according to claim 30, it must be present as part of an aryl or arylalkyl anionic moiety, a heteroaryl or heteroarylalkyl anionic moiety, or a neuraminic or sialic acid-containing moiety modified by substitution at the 4-position as required by claim 17. For analogous reasons, claim 31 is indefinite because it recites anionic moieties (see, e.g., page 2, line 3) which do not satisfy the structural requirements required for anionic moieties by independent claim 17. Finally, claim 31 is indefinite because the preamble to the claim indicates that anionic-containing moieties are to be listed; however, moieties at, e.g., lines 5-7; page 2, line 6, last moiety; and page 2, line 7; are cationic-containing moieties. This claim should be compared with claim 39 of the parent application. Clarification is required.

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5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. *Joy Technologies Inc. v. Quigg*, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In *re Hoeschele*, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In *re Clinton*, 188 USPQ 365, 367 (CCPA 1976); In *re Thompson*, 192 USPQ 275, 277 (CCPA 1976).

6. Claims 17-36 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 98/03572. The WO Patent Application '572 issued based upon Applicants' priority

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document PCT/AU97/00446, and is available as prior art under 35 U.S.C. 102(b) against the instant claims in the absence of a valid claim for priority. See also paragraph 1 above.

7. Claims 17-26, 28, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by the Roy et al article (J. Chem. Soc., Chem. Comm., 1993, pages 264-265). The Roy et al article teaches sialic acid residues attached to linear polylysine having a molecular weight of 69,000. Attachment is through a linking group comprising a thioether, an amide, and a substituted alkyl chain, to the amine group of lysine sidechains. See page 264, column 1, last paragraph, and compound 3. Because the modified polylysine of the Roy et al article has the same structure claimed by Applicants, inherently it will have antiviral activity to the same extent claimed by Applicants.

8. Claims 17-36 are rejected under 35 U.S.C. 103(a) as being obvious over Jansen et al in view of the WO Patent Application '595. Jansen et al teach treating viral infections, including HIV infections and influenza infections, with polypeptides whose amino groups and/or other basic functional groups have been modified to have a negative charge. The groups having a negative charge, which can be carboxylic acid groups, can be bound to the amino groups of the polypeptide through amide linkages. Additional anionic functional groups such as phosphate, sulfate, and carboxyl groups, can be incorporated into the polypeptide where possible. The polypeptides are preferably polyamino acids, including polylysine, or albumin. The molecular weight of the polypeptides can be 70,000. The modified proteins or polypeptides are administered in combination with pharmaceutically acceptable excipients. See, e.g., the Abstract; column 4, line 60 - column 5, line 9; column 5, line 24 - 7, line 47; and column 9, lines 33-45. Jansen et al teach that it is the presence of many anionic groups on the polypeptide, rather

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than the exact chemical identity of the polypeptide or of the anionic groups, which is the important factor in the polypeptide exhibiting antiviral activity (see, e.g., column 4, lines 65-67, and column 9, lines 15-28). Jansen et al do not teach polypeptides such as albumin or polylysine having Applicants' specific anionic groups of instant claims 31-33. The WO Patent Application '595 teaches various anionic groups which can be incorporated into a polylysine dendrimer used as an antiviral compound. See, e.g., Tables 2 and 3 and claim 26. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use the anionic groups of the WO Patent Application '595 to modify the polypeptides of Jansen et al because substitution of one functionally equivalent anionic group for another is prima facie obvious, because Jansen et al teach that the identity of the polypeptide and the anionic groups are not critical and Jansen et al is not limited to any particular anionic groups, and because the resultant compounds have only the antiviral activity which is to be expected in view of Jansen et al and the WO Patent Application '595.

9. Claims 17-21, 24-29, 31, and 33-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Mandeville, III et al (U.S. Patent No. 6,034,129). Mandeville, III et al '129 teaches linear, non-carbohydrate polymers having a plurality of sidechain groups wherein at least one of the side chain groups is a quaternary ammonium group such as trimethylammoniumpropyl and trimethylammoniumhexyl. The polymers preferably have molecular weights from about 2000 Daltons to about 150,000 Daltons. Polymers comprising amine-containing and amide-containing monomers are exemplified. The quaternary ammonium groups can be linked to the polymer backbone through spacer groups comprising, e.g., ether groups or alkyl chains; can be added to activated polymers by formation of an amide linkage; or

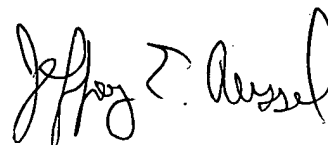
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can be formed by alkylation of amine groups already present in the polymer. The polymers are combined with pharmaceutically acceptable carriers or diluents for administration in vivo. See, e.g., the Abstract; column 3, lines 18-31; column 4, lines 4-21 and 38-51; column 5, lines 62-66; column 6, lines 41-44 and 58-67; column 7, lines 1-9; and Examples 3, 4, and 12. Because the polymers of Mandeville, III et al '129 have the same structure claimed by Applicants, inherently they will have antiviral activity to the same extent claimed by Applicants. Because the same polymers are being administered to the same animals by the same method steps, inherently viral infections in the animals will be prevented to the same extent in Mandeville, III et al '129 as is claimed by Applicants.

10. The examiner maintains his position for the reasons set forth during prosecution of the parent application.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
April 18, 2003